# EEP-News

## Information on Life Science law

## EHLERS, EHLERS & PARTNER was a finalist at The Lawyer European Awards 2009 ceremony in the category "European Niche Law Firm of the Year"!


Dear Ladies and Gentlemen,

The parliamentary elections in Germany have resulted in a coalition of Christian Democrats and Free Democrats. The orientations of the coalition partners have been stipulated in the coalition agreement, which deals to a large extent with new ideas regarding the future healthcare policy. It is to be questioned, how realistic the agenda of the coalition partners might be in the current difficult economic environment existing in this legislative period. The task, in particular for the new team in the federal Ministry of Health, is anything but easy. Due to the lack of a broad consent between the coalition partners, we should expect a lively discussion in the near future.

In any case, we are very much looking forward to a joint and exciting collaboration in the future.

Sincerely yours

**EHLERS, EHLERS & PARTNER**
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**News**

We are happy to announce that Dr. Cord Willhöft, LL.M (KCL) will become partner of our Life Science law firm Ehlers, Ehlers & Partner in Munich with effect from 1 January 2010. After completing his studies in Göttingen and London and his dissertation concerning European healthcare issues, Cord Willhöft started his career as a life science lawyer and joined the law firm in 2006. He is the legal counsel of many renowned international pharmaceutical companies and manufacturers of medical devices with respect to compliance and regulatory issues, as well as in questions related to reimbursement in the healthcare sector. In addition, Cord Willhöft advises healthcare service providers in matters with respect to professional legal regulations and accounting procedures.

## News

## Pharmaceuticals in the assessment by G-BA

The guarantee of effective financing and a solid financial bias of the Statutory Health Insurance (Gesetzliche Krankenversicherung – GKV) is one of the urgent tasks for legislators all over the world. According to this the German legislator has created a considerable instrument in order to concrete the bidding of economy to orient the current system towards the aspects of economy and efficiency. This is also of particular importance for the pharmaceutical sector.
In this context benefit assessments of pharmaceuticals and the recently launched cost-benefit analysis will become more and more important in the future so that the competent authority – the Federal Joint Committee (G-BA) – has been given a special role. Already with the GKV-WSG (Act to Strengthen Cost Effectiveness in Statutory Health Insurance) the lawmaker has created the opportunity to run cost-benefit assessments for pharmaceuticals – in addition to the benefit assessment of pharmaceuticals.
The object of the cost-benefit assessment is - simply speaking – the calculation of the therapeutic additional benefit of innovative pharmaceuticals in relation to the costs and in comparison to other pharmaceuticals and ways of therapy. However, in detail many things are not clarified yet, especially the question how to actually understand and to measure the benefit of a pharmaceutical. The main players of the benefit assessment in the GKV, the G-BA on the one side and the Institute for Quality and Efficiency in Health Care (IQWiG) on the other side in particular don't use a common apprehension for "benefit" while the IQWiG's methods are particularly contrary to other, international accepted proceedings like NICE.
Which parameters have to be actually noted thereby, the law doesn't answer. In particular, it isn't ruled unitarily from which perspective a medical intervention will be assessed having regard to its benefit. In addition to that the IQWiG's own Method's Papers partially contain contradictions in relation to the Social Code Book V (SGB V): While the law explicitly asks for consideration of life quality in the assessment of pharmaceuticals, the Institute merely wants to use clinical measures which primarily refer to mortality and morbidity. The aspect of patient's satisfaction comes only into consideration as secondary target dimensions. Furthermore the understanding of "benefit" used by the IQWiG does not comply with the Code of Procedure of the G-BA which basically differentiates between "benefit" and "necessity". In general it can be considered that the benefit defined by the G-BA should be more comprehensive than the IQWiG's one. Already these aspects show how the implementation of the described instruments is tainted with considerable faults causing uncertainty amongst physicians, patients and the pharmaceutical companies concerned.
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## Foreign Manufacturers Legal Accountability Act of 2009

The Foreign Manufacturers Legal Accountability Act of 2009 (hereafter referred to as "**FMLA Act 2009**") has been introduced to the Senate of the United States (US) on August 6, 2009. Although the FMLA Act 2009 is currently only at the first step of the legislative procedure, i.e. it has been referred to the Committee of Finance which will revise it before the Act goes into a general debate, it may have, once enacted, a major impact on pharmaceutical manufacturers importing their products into the United States. Therefore, it is recommended to pharmaceutical manufacturers to already take the potential impact of the FMLA Act 2009 on their business into consideration. The FMLA Act 2009 shall require foreign manufacturers of products imported into the US to establish a registered agent in the US who is authorised to accept service of process. The FMLA Act 2009 requires the registered agent to be located in a state with a substantial connection to the importation, distribution, or sale of the product. Further, by establishing a registered agent, foreign manufacturers consent to the personal jurisdiction of the State or Federal Courts of the State in which the registered agent is located. According to Section 6 (2) of the FMLA Act 2009, manufacturers which have not registered an agent (i.e. 180 days after the enforcement of this Act) may not import their products into the US. In consequence, the FMLA Act 2009 is able to impose an import ban on pharmaceutical manufacturers if they do not register an agent in the US. Regardless the actual need for such a legislation besides the already existing *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* (concluded in March 1954), the FMLA Act 2009 might serve as an incentive for other countries to impose the same obligations on their importers and could cause additional and extensive administrative hurdles for exporting pharmaceutical manufacturers worldwide.
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## Bonus systems infringe the German Act for the Advertisement of Medicinal Products, ("HWG") even if they are granted for the purchase of products from the complete and in part non-medicinal assortment

The Federal High Court ruled on 26.03.2009 (file no.: I ZR 99/07) that bonuses granted in return for the purchase of products from the product range of a pharmaceutical manufacturer, which are partly non-medicinal products, infringe the HWG. A distinction is made between product-related and company-related advertisement, i.e. only product-related advertisement falls within the scope of the HWG. In the past, companies could avoid infringements of the HWG by relating the bonus system not to single medicinal products but to the entire product range of the company. The new ruling of the Federal High Court compels companies, again, to more restrictive advertisement with respect to product-related advertisement.
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## European Court of Justice decides on interpretation of Section 2 German Patent Act

According to a decision of 12.11.09 the German Federal Court of Justice (BGH) submitted to the European Court of Justice (ECJ) questions regarding the interpretation of Section 2 of the German Patent Act, which bans the patenting of inventions where their commercial exploitation would be contrary to ordre public or morality. Pursuant to Section 2 Para. 2 1st sentence no. 3 of the German Patent Act, patents are not granted for uses of human embryos for industrial or commercial purposes. The interpretation of this provision depends on the interpretation of the identically worded provision of Article 6 of Directive 98/44/EC (Biopatent Directive), which was transposed into German Law with Section 2 of the German Patent Act. The decision of the ECJ will have great influence on the interpretation of the terms “human embryos” and “use for industrial or commercial purposes” and will therefore be of importance for future research activities. We do not expect a judgement before mid 2011.
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## „kick – backs“ in the clinical sector – new developments in legal practice

The latest judgement of the Higher Regional Court of Düsseldorf from 01.09.2009, file no.: I-20 U 121/08, advanced a more restrictive view on payments from a clinic to a general practitioner for the hospitalisation and the preoperative and postoperative treatment of patients. The Court ruled that such practice infringes sec. 31 of the professional code for doctors, whereupon a payment for the hospitalisation of a patient is held illegal. Moreover such a practice is in contrast to sec. 115 a, b of the Social Code V, whereupon the outpatient care is to be paid by the Association of Statutory Health Care Physicians and not by a clinic.
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